Exhibit J

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Manufacturing and Product Quality
Division International Drug Quality
International Compliance Branch
10903 New Hampshire Avenue
Building #51, Room 4234
Silver Spring, MD 20993

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August 13, 2014

Baohua Chen
President and General Manager
Zhejiang Huahai Pharmaceuticals Co., Ltd.
Coastal Industrial Zone
Chuannan No. 1 Branch
Duqiao, Linhai, Zhejiang Province 317024
Peoples Republic of China

Reference: FEI 3003885745

Dear Mr. Chen:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your Active Pharmaceutical Ingredient (API) manufacturing facility in Linhai, China by Investigator Laurie Bem Frazier during the period of May 19, 2014 to May 23, 2014.

Based on the profile class covered during the inspection, we are classifying your facility as acceptable. This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practices (CGMPs).

Please be advised that all manufacturers must register annually as required by 21 C.F.R. § 207.40. Information on how to register is available at http://www.fda.gov/cder/drls/registration_listing.htm.

Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the Freedom of Information Act and 21 C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at the above address or number.

Sincerely,

/Alicia Mozzachio for

Alicia Mozzachio
Branch Chief
Division of International Drug Quality

Establishment Inspection Report	**FEI:**	**3003885745**
Zhejiang Huahai Pharmaceutical Co. Ltd.	**EI Start:**	**05/19/2014**
Linhai, China	**EI End:**	**05/23/2014**

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SUMMARY

This inspection of a generic active pharmaceutical ingredient (API) manufacturer was conducted in accordance with CP 7356.002F Active Pharmaceutical Ingredient Manufacturers Inspection per FACTS assignment number 9401624 to provide GMP coverage for multiple CDER-EES requests. This inspection covered the manufacturing of Nevirapine and Losartan Potassium, both profile CSN. Inspection was preannounced by OMPTO/DMPTI. The firm displayed documentation showing that they are registered with the US FDA as an API manufacturer and have paid their GDUFA fees for 2014.

Previous inspection of the firm dated 9/8/2010 was classified as NAI, no action indicated with no FDA 483 issued.

Establishment Inspection Report	FEI:	**3003885745**
Zhejiang Huahai Pharmaceutical Co. Ltd.	EI Start:	05/19/2014
Linhai, China	EI End:	05/23/2014

Current inspection found the firm continues to be a manufacturer of both intermediates and APIs which are sold to countries around the world including the US; intermediates are not sold to the US market. The therapeutic areas of the firm's products are: anti-hypertensive; anti-depressant; anti-psychotic; anti-diabetes; anti-convulsant; anti-epileptic; and anti-HIV/AIDS. This GMP inspection covered the following Systems: Quality System, Facilities and Equipment System, Materials System, Production System, Packaging and Labeling System, and Laboratory Controls System. No inspectional observations were made and no FDA 483 was issued.

No refusals were encountered and no samples were collected during this inspection.

ADMINISTRATIVE DATA

Inspected firm:	Zhejiang Huahai Pharmaceutical Co. Ltd.
Location:	Coastal Industrial Zone Chuannan No. 1 Branch Duqiao, Linhai City, Zhejiang Province 317024 China
Phone:	+86 576 85016003
FAX:	+86 576 85016013
Mailing address:	Coastal Industrial Zone Chuannan No. 1 Branch Duqiao, Linhai City, Zhejiang 317024 China
Website	www.huahaipharm.com
Dates of inspection:	5/19/2014, 5/20/2014, 5/21/2014, 5/22/2014, 5/23/2014
Days in the facility:	5
Participants:	Laurie Bem Frazier, Investigator

I displayed Credentials and exchanged business cards with Baohua Chen, President and General Manager of the firm. Mr. Chen was present for the opening and closing meetings of this inspection.

HISTORY

Zhejiang Huahai Pharmaceutical Co., Ltd., hereby referred to as the firm, is a manufacturer of pharmaceuticals, intermediates, and APIs; this site is a manufacturer of intermediates and APIs only. The firm explained to me that they hold 17 ANDAs and 48 DMFs; and have approximately 3800 employees worldwide. A second manufacturing site is located in Xunqiao, Linhai. Since the previous inspection the firm reported that they have acquired Solco HealthCare US, which is a

pharmaceutical finished dosage form (FDF) marketing and sales company. The firm's locations in China are:

Xunqiao Site: API, FDF, R&D	Chuannan Site: API, Intermediates	Huanan Site: Intermediates
Shanghai Huabo: Bio R&D	Shanghai Syncore: API R&D	Shanghai Prinbury: FDF R&D
Shanghai Sales Office	Hangzhou Sales Office	Huahai US Inc.: Sales, R&D

Previous inspection of the firm was dated 9/6 – 8/2010 and was classified as NAI, no action indicated with no FDA 483 Inspectional Observations issued.

Other changes since the previous FDA inspection the firm reported personnel changes and commissioning of Facility 2 Workshop 8.

The firm stated that at this site there are 1385 full time employees with 112 in Quality Assurance (QA)/Quality Control (QC) and 981 in production. Regular hours of operation for office staff are Monday through Friday 8:00am to 5:00pm with production operating on 3 shifts for 24 hour coverage 7 days a week.

Official correspondence should be addressed to:

Chen Baohua, President and General Manager
Zhejiang Huahai Pharmaceuticals Co., Ltd.
Coastal Industrial Zone
Duqiao, Linhai, Zhejiang Province 317016
Peoples Republic of China

The firm's US Agent is:
Huahai US Inc.
2002 Eastpark Blvd.
Cranbury, NJ 08512
Attn: Dr. Xiaodi Guo

This inspection noted the following CDER-EES requests:

